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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,499	02/08/2002	Neil M. Wolfman	8702.0100-00	3454

7590 08/21/2003

c/o Rebecca M. McNeill
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
1300 I Street, N.W.
Washington, DC 20005-3315

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/21/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,499

Applicant(s)

WOLFMAN ET AL.

Examiner

Janet L. Andres

Art Unit

1646

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-118 is/are pending in the application.
- 4a) Of the above claim(s) 21-118 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. 6) ☐ Other: _____

Art Unit: 1646

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 10 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden to search Groups I and IV, since they are in the same class and subclass and the searches are thus co-extensive. This is not found persuasive because classification in the same subclass does indicate that the searches are co-extensive. The polypeptides have different sequences and require entirely separate searches of the databases.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure is objected to because of the following informalities: There are sequences in figures 7 and 11 that lack sequence identifiers. In addition, the linker sequences on p. 18, line 9, and p. 21, line 21, fall within the requirements of the sequence rules and require identifiers.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1, 2, 4, 5, 15, 16, 19, and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 200043781.

Art Unit: 1646

WO 200043781 teaches GDF- 8 from several species in figure 11. It further teaches that the proregion of GDF-8 is inhibitory (figures 14 and 15). Variants of the proregion, including altered proteolytic sites and altered glycosylation sites, are taught on pp. 20-21. WO 200043781 thus anticipates claims 1, 4, 5, 15, 16, and 19. While the proregion taught by WO 200043781 is longer than that taught by Applicant, encompassing 6 additional N-terminal amino acids (see site indicated in figure 13 and sequence alignments of figure 11), both the rat sequence and the corresponding human sequences taught by WO 200043781 are > 90% identical to instant SEQ ID NO: 5, anticipating claim 2. Purification tags are taught on p. 19, anticipating claim 20.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 200043781.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1646

WO 200043781 teaches as set forth above but fails to teach a GDF-8 inhibitor that is identical to SEQ ID NO: 5, as claimed in instant claim 3 and encompassed by claims 1 and 2. However, on p. 56, lines 23-24, WO 200043781 teaches that the sequence NENSE is inhibitory and further teaches that this sequence is found in the proregion of GDF-8. Thus, it would be obvious to one of ordinary skill in the art to devise a molecule with NENSE at the N-terminus, and a C-terminus corresponding to that of the proteolytic processing site that generates the proregion (indicated for human GDF-8 in figure 17). One of ordinary skill would be motivated to do so because, based on the teachings of WO 200043781, one of ordinary skill would expect such a peptide to be inhibitory.

7. Claims 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 200043781 in view of U.S. patent 5,723,125 (Chang et al., 1998).

WO 200043781 teaches as set forth above but fails to teach GDF-8 proregion/IgG1 Fc or IgG4 Fc fusion proteins, as claimed in instant claims 7- 14 and encompassed by claim 6. The '125 patent teaches fusion of interferon with IgG1 or IgG4 as a means of prolonging the half life of the interferon (column 2, lines 16-59, column 5, lines 54-59). It would have been obvious to one of ordinary skill in the art to combine the teachings of WO 200043781 with the '125 patent to produce Fc fusion proteins. One of ordinary skill would have been motivated to do so because WO 200043781 teaches useful protein therapeutic inhibitors of GDF-8 and the '125 patent teaches methods of improving the efficiency of protein therapeutic agents.

8. Claims 6 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 200043781 in view of U.S. patent 5,116,944 (Sivam et al., 1992).

WO 200043781 teaches as set forth above but fails to teach GDF-8 proregion/albumin fusions, as claimed in instant claim 17 and encompassed by claim 6. The '944 patent teaches fusion of proteins with albumin as a means of prolonging their half lives and reducing toxicity (column 4, lines 34-49). It would have been obvious to one of ordinary skill in the art to combine the teachings of WO 200043781 with the '944 patent to produce albumin fusion proteins. One of ordinary skill would have been motivated to do so because WO 200043781 teaches useful protein therapeutic inhibitors of GDF-8 and the '944 patent teaches methods of improving the efficiency of protein therapeutic agents.

9. Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 200043781 in view of U.S. patent 4,179,337 (Davis et al., 1979).

WO 200043781 teaches as set forth above but fails to teach GDF-8 proregion/polymer fusions, as claimed in instant claim 18 and encompassed by claim 6. The '337 patent teaches fusion of proteins with polyethylene glycol as a means of reducing immunogenicity (column 2, lines 11-23). It would have been obvious to one of ordinary skill in the art to combine the teachings of WO 200043781 with the '337 patent to produce pegylated GDF-8 propeptides. One of ordinary skill would have been motivated to do so because WO 200043781 teaches useful protein therapeutic inhibitors of GDF-8 and the '337 patent teaches methods of increasing the usefulness of therapeutic agents.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1646

11. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are drawn to modified peptides, yet encompass SEQ ID NO: 5, which is an unaltered fragment of GDF-8. One of skill in the art would not be able to determine how this peptide was modified and thus would not be able to determine what Applicant intended this limitation to encompass. Further, since there are no functional limitations, one of skill in the art would not be able to determine the extent of "modification" that would be tolerated within the scope of the claims.

NO CLAIM IS ALLOWED.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
August 20, 2003


JANET ANDRES
PATENT EXAMINER